(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
8 December 2005 (08.12.2005)

PCT

(10) International Publication Number
WO 2005/115521 A1

(51) International Patent Classification[7]: A61M 25/00, 39/10, F16L 31/00

(21) International Application Number: PCT/US2004/015464

(22) International Filing Date: 14 May 2004 (14.05.2004)

(25) Filing Language: English

(26) Publication Language: English

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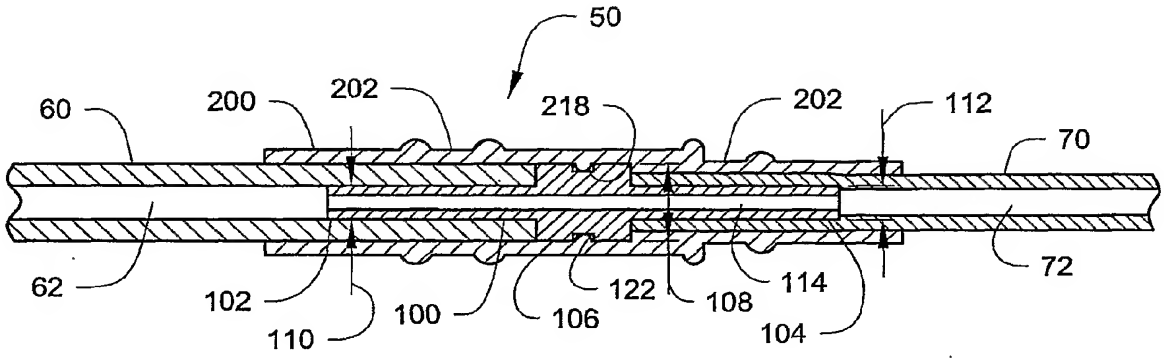
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: MEDICAL TUBING CONNECTOR ASSEMBLY INCORPORATING STRAIN RELIEF SLEEVE



(57) Abstract: A connector assembly for interconnecting separate sections of tubing, e.g., medical tubing, and a method for using the same. Connector assemblies in accordance with embodiments of the present invention may be a two-piece construction having a connector pin and a connector sleeve. In addition to providing secure, substantially leak-free coupling of the tubing sections, connector assemblies as shown and described herein may also provide strain relief to the tubing interconnection.

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MEDICAL TUBING CONNECTOR ASSEMBLY INCORPORATING STRAIN RELIEF SLEEVE

TECHNICAL FIELD

The present invention relates generally to medical devices and, more particularly, to connector assemblies for joining two pieces of medical tubing, e.g., catheters, wherein the connector assemblies are operable to provide strain relief to the catheter connection.

BACKGROUND

In many medical applications, it is necessary to connect one section of medical tubing, e.g., a catheter, with another. Generally speaking, it is important that these connections be relatively secure and stable so that the tubing does not separate or develop leaks at the connection point. Security and leak-resistance take on special importance in applications where the tubing sections are implanted in a human body.

One procedure that necessitates implantation of medical tubing into the body involves the use of an implantable drug infusion pump. Such pumps are often used to control pain and/or spasticity, as well as to provide one or more drugs or fluid medications to a particular location within the body. For instance, a typical implant procedure may involve implanting a drug infusion pump into a cavity or subcutaneous pocket in the body and delivering a drug, via a catheter(s), to an epidural space or intrathecal space of the spinal column or to a particular location within the brain. In this exemplary application, a catheter assembly having two or more catheter sections, e.g., a thin-walled distal section (near the implantation site) and a thicker-walled proximal section (connected directly to the infusion pump), may be used to deliver the drug to the desired site.

The distal catheter section may be positioned in the desired location in the body and then connected to the proximal catheter section by use of a medical tubing connector. The connection may be made by inserting one end or prong of the connector into a lumen of one catheter section (e.g., the proximal section) and the other end of the connector into the lumen of the other catheter section (e.g., the distal section) and then sliding both catheter sections towards one another (toward the middle of the connector). The proximal section may then be connected to the drug infusion pump.

While adequate, difficulties have been encountered in the manufacture and use of such prior art medical connectors. For example, these connectors, which have been sized to fit within the lumens of the catheter tubing sections, are small and may be difficult to manipulate during implantation. Moreover, because some of these connectors fit entirely within the lumens of the respective catheter sections, it is often difficult for the implanting physician to be sure that the interface between catheter sections is positioned at, or even near, the center of the connector, i.e., it may be difficult to center the catheter sections on the connector. Misalignment of the connector can result in a weakened connection that is more likely to separate and/or develop leaks. Other potential problems include: lack of ability to adequately secure the catheters relative to one another; and inability to provide sufficient strain relief to the connection.

SUMMARY OF THE INVENTION

Embodiments of the present invention provide connector assemblies and methods for connecting sections of medical tubing that may overcome some or all of the problems identified above. For example, in one embodiment, a connector assembly is provided having a connector pin. The connector pin includes: a first end portion, a second end portion, and a lumen extending between the first end portion and the second end portion; and a central portion located between the first end portion and the second end portion, wherein the central portion has an outer dimension that is larger than an outer dimension of both the first and second end portions. The assembly also includes a tubular connector sleeve comprising a first end, a second end, and a passageway extending between the first end and the second end. The passageway is stepped such that it has: a first diameter between the first end of the sleeve and a stop surface located in the passageway; and a second diameter between the stop surface and the second end of the sleeve, wherein the first diameter is greater than the second diameter.

In another embodiment, a method of interconnecting sections of medical tubing is provided, wherein the method includes inserting a first end portion of a connector pin into a first medical tube. The connector pin includes: a second end portion, wherein a lumen extends between the first end portion and the second end portion; and a central portion located between the first and second end portions, wherein the central portion includes an outer dimension that is greater than an outer dimension of either of the first and second end portions. The method also includes: inserting the second end portion into a second

medical tube; sliding a tubular sleeve over the first and second medical tubes and the connector pin; and engaging a first lock portion located within a passageway of the sleeve with a second lock portion of the connector pin.

The above summary is not intended to describe each embodiment or every implementation of the present invention. Rather, a more complete understanding of the invention will become apparent and appreciated by reference to the following Detailed Description of Exemplary Embodiments and claims in view of the accompanying figures of the drawing.

BRIEF DESCRIPTION OF THE VIEWS OF THE DRAWING

The present invention will be further described with reference to the figures of the drawing, wherein:

Figure 1 is a perspective view of a connector assembly in accordance with one exemplary embodiment of the invention, the connector assembly for use with coupling separate sections of medical tubing, e.g., catheters;

Figure 2 is a cross-sectional view of the connector assembly of Figure 1;

Figure 3 is a perspective view of a connector pin in accordance with one embodiment of the present invention;

Figure 4 is a perspective view of a connector pin in accordance with another embodiment of the present invention;

Figure 5 in a perspective view of a tubular connector sleeve in accordance with one embodiment of the invention;

Figures 6-7 illustrate an exemplary method for assembling the connector assembly of Figures 1 and 2; wherein Figure 6 illustrates the connector pin during insertion into the tubular connector sleeve; and Figure 7 illustrates the connector pin after complete insertion into the sleeve.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

In the following detailed description of illustrative embodiments of the invention, reference is made to the accompanying figures of the drawing which form a part hereof, and in which are shown, by way of illustration, specific embodiments in which the invention may be practiced. It is to be understood that other embodiments may be utilized and structural changes may be made without departing from the scope of the present

invention. Unless stated otherwise herein, the figures of the drawing are rendered primarily for clarity and thus may not be drawn to scale.

Generally speaking, the invention is directed to apparatus and methods for securely coupling two pieces of tubing to one another. While the invention may find application to most any type of tubing, it is especially well-suited to the joining of separate sections of medical tubing, e.g., catheters. For instance, connector assemblies in accordance with embodiments of the present invention may be used to couple a drug infusion catheter (extending from a drug infusion pump) to a brain infusion catheter located at a predetermined location within a human brain. Accordingly, while the following exemplary embodiments are described with reference to such infusion catheter couplings and methods, those of skill in the art will realize that the invention may find use with most any type of tubing application.

Figures 1 and 2 illustrate a medical tubing connector assembly 50 in accordance with one embodiment of the invention. The assembly 50 may include a medical connector, e.g., connector pin 100 (see Figure 2), and a strain relieving, tubular connector sleeve 200. A first medical tubing section, e.g., first catheter 60, and a second tubing section, e.g., second catheter 70, may couple to the connector pin 100 as further described below. Once so coupled, the tubular sleeve 200 may slide over the connector pin 100 and the catheters 60 and 70 as shown, resulting in a secure and substantially leak-free coupling of the independent catheters.

Moreover, as further explained below, the connector assembly 50 may provide strain relief for the catheters 60 and 70. That is, the tubular connector sleeve 200 may provide resistance to tearing of the catheters 60 and 70 by the ends of connector pin 100 and further resist forces that would tend to separate, or allow relative movement of, the connector pin 100 relative to the catheters 60 and 70. The connector assembly 50 may also include securing features, e.g., suture grooves 202 on an exterior surface of the sleeve 200, to permit securing the sleeve 200 over the connector pin 100 and for fixing of the assembly relative to local tissue 82, e.g., with a suture 80.

Figure 2 illustrates a cross section of the connector assembly 50. In this view, the connector pin 100 is illustrated as a generally longitudinal member having a first end portion 102 (also shown in Figure 3) operable to fit within a lumen 62 of the first catheter 60 with a small clearance fit or, alternatively, an interference fit, and a second end portion 104 operable to fit within a lumen 72 of the second catheter 70 with small clearance, or

interference, fit. The fits between the connector pin 100 and the catheters 60 and 70 may be sufficient to hold the catheters in place, relative to the connector pin, under normal operating circumstances.

The connector pin 100 may also include a central portion 106 positioned between the first end portion 102 and the second end portion 104. The central portion 106 has an outer or external dimension, e.g., a diameter 108, that is preferably larger than at least one of: an outer or external dimension (e.g., a first diameter 110) of the first end portion 102; and an outer or external dimension (e.g., a second diameter 112) of the second end portion 104. The connector pin 100 may also include a lumen 114 extending through the pin from the first end portion 102 to the second end portion 104. The lumen 114, in the illustrated embodiment, may pass completely through the connector pin 100 so as to permit fluid communication between the first catheter 60 and the second catheter 70.

Figure 3 is an enlarged perspective view of the exemplary connector pin 100 of Figure 2. The connector pin 100 may be made of most any biocompatable material including various metals and plastics, e.g., noble metals such as titanium. Moreover, the connector pin 100 may be an integral component or, alternatively, the enlarged central portion 106 may be made of a secondary material which may, for example, be molded to a shaft formed by the first and second end portions. In the illustrated embodiments, the lumen 114 may be generally concentric to the longitudinal axis of the connector pin 100. The end portions 102 and 104 may extend a sufficient distance from the central portion 106 to ensure adequate engagement with the catheters 60 and 70. Moreover, while the end portions 102 and 104 may be most any shape, they are preferably cylindrical to correspond with the shape of the catheter lumens into which they are inserted. The enlarged central portion 106 may also be of most any shape but is also preferably cylindrical to correspond to the shape of the tubular connector sleeve 200 as further described below.

In the embodiment illustrated in Figure 3, enlarged central portion 106 may include an outer surface 116 bounded by stop surfaces 118 and 120, which are generally perpendicular to a longitudinal axis of the connector pin 100. The stop surfaces 118 and 120 may provide a positive stop against which the ends of the catheters 60 and 70, respectively, abut when the connector pin 100 is inserted therein. By providing the stop surfaces 118 and 120, the physician may ensure that each catheter is properly engaged with the connector pin 100. The stop surface 120 may also assist the physician in locating

the tubular connector sleeve 200 relative to the connector pin 100 as further described below.

The central portion 106 may further include a lock portion (a portion operable to positively lock with another component) operable to secure the connector pin 100 to the tubular connector sleeve 200. In the illustrated embodiments, the lock portion may be formed by a recess, e.g., a circumferential lock groove 122, formed in the outer surface 116 of the central portion 106. The lock groove 122 may engage a corresponding lock portion associated with the tubular connector sleeve 200 as further described below.

An alternative connector pin 130 illustrated in Figure 4 (which is similar in many respects to the connector pin 100 described above) may include end portions 132 and 134 that have axial tapers 136 and 138, respectively. The axial tapers 136 and 138 may assist in insertion of the end portions 132 and 134 into receiving ends of the medical tubing. The end portions 132 and 134 may also include circumferentially depressed sections 140 and 142, respectively. The circumferentially depressed sections 140 and 142 may assist in securing the medical tubing to the end portions 132 and 134. That is, since medical tubing is typically made of a generally compliant material, the inner surface of the tubing (e.g., catheters 60 and 70 of Figure 2) will generally comply with the surface of the end portions of the connector pin 130, including the depressed sections 140 and 142. Other connector pin embodiments may be similar to those described in U.S. Pat. No. 5,405,339 to Kohnen et al.

Figure 5 illustrates the exemplary tubular connector sleeve 200 of Figures 1 and 2. The connector sleeve 200 may be made of a flexible and resilient material operable to receive the catheters 60 and 70 and the connector pin 100 therein. Once assembled, the connector sleeve 200 may provide not only secure coupling of the mating components, but also strain relief to the catheter ends.

The connector sleeve 200 may include a passageway 208 extending from a first end 204 of the sleeve to a second end 206. In the illustrated embodiment, the passageway 208 is cylindrical and stepped. The step may be defined, for example, by providing a first section 209 of the passageway 208 extending from the first end 204 of the sleeve 200 to a stop surface 212 located within the passageway 208. The passageway 208 may, in the first section 209, have a first interfacing dimension, e.g., may be defined by a first diameter 210. The passageway 208 may also include a second section 211 that extends from the stop surface 212 to the second end 206 of the sleeve 200. The second section 211 may

have a second interfacing dimension, e.g., may be defined by a second diameter 214. The first interfacing dimension of the passageway 208 may be greater than the second interfacing dimension, e.g., the first diameter 210 may be greater than the second diameter 214.

As used herein, the term "diameter" may refer to the length of the longest straight line segment passing through the center of a cross-section of a respective object, e.g., the passageway 208, and terminating at the object periphery, e.g., at the walls of the passageway. Thus, the term "diameter" may be used to describe an effective diameter of any component of the present invention (e.g., sleeve, sleeve passageway, connector pin, lumen, and tubing section) whether it has a circular or non-circular cross-sectional shape, e.g., oval.

While the shape of the passageway 208 is described and illustrated herein as including two generally uniform stepped bores, the actual shape of the passageway and, for that matter, the shape of the connector sleeve 200 itself, may be altered without departing from the scope of the invention.

The first section 209 of the sleeve 200 may be defined by an inner surface 216. The inner surface or wall 216 may include a lock portion, e.g., an inwardly extending protrusion 218. The protrusion 218 is preferably circumferential and operable to engage a mating lock portion, e.g., the lock groove 122 (see Figure 3) of the connector pin 100, when the latter is correctly positioned within the connector sleeve (see Figure 2).

The connector sleeve 200 may also include suture grooves 202. In the illustrated embodiment, the connector sleeve 202 may include two separate suture grooves 202 defined by outwardly extending circumferential protrusions 203.

The material used to make the connector sleeve 200 is preferably flexible and resilient. While various polymers are suitable, materials that achieve these objectives may include silicone and polyurethane. In other embodiments, the sleeve 200 could be made of a less compliant, e.g., relatively rigid, material.

Assembly of the connector assembly of Figures 1 and 2 will now be described with reference to Figures 6 and 7. These figures are cross-sectional views of the exemplary connector assembly 50 of Figures 1 and 2 in various stages of assembly. The connector assembly is described herein with respect to a drug or fluid medication delivery system using an implanted drug pump (not shown) operable to deliver drugs to a location within the brain. As stated above, however, this application is not limiting.

A catheterization procedure may begin with the placement of a distal catheter section (e.g., the catheter 70 of Figure 2). This section of catheter may be inserted in a manner known to those skilled in the art. Before, during, or after proper placement of the distal section of the catheter 70 has been verified, a subcutaneous pump pocket may be prepared at the desired anatomical location within a patient's body. A proximal catheter section, e.g., catheter 60 of Figure 2, may then be tunneled from the distal catheter section to the pump pocket. At this point in the procedure, the adjacent ends of the distal and proximal catheter sections, e.g., the coupling ends of catheters 60 and 70 that are shown in the Figures, may be connected using the connector assembly described herein.

As represented in Figure 6, the connector sleeve 200 may first be slid over the coupling end of the second catheter 70. The sleeve may be slid sufficiently onto the second catheter 70 to permit the physician unimpeded access to the coupling end of the second catheter. The second end portion 104 of the connector pin 100 (in some embodiments, the connector pin 100 may be symmetrical such that the first end portion 102 is identical to the second end portion) may be inserted into the lumen 72 of second catheter 70. The first end portion 102 may be similarly inserted into the lumen 62 of the first catheter 60.

The end portions 102 and 104 of the connector pin 100 are preferably inserted into their respective catheter sections 60 and 70 until they contact the respective tubing stop surfaces 118 and 120. In practice, the implanting physician may effect the catheter connections by grasping the enlarged central portion 106 of the connector pin 100.

The outer diameter of each end portion 102 and 104 may be slightly larger than the undeflected diameter of the lumens of the respective catheters 60 and 70. Alternatively, the outer diameters of the end portions 102 and 104 may be the same as, or slight less than, the diameters of the lumens of the respective catheters. The resulting fit between the components may result in not only secure connection of the catheters 60 and 70, but may also provide substantially leak-free flow of fluid between the catheters.

Once the catheters 60 and 70 are coupled to the connector pin 100 as generally illustrated in Figure 6, the tubular connector sleeve 200 may be slid over the connector pin 100 in the direction 220 until the second stop surface 120 of the connector pin 100 contacts the stop surface 212 of the connector sleeve 200 as shown in Figure 7. Prior to reaching the position illustrated in Figure 7, the circumferential protrusion 218 of the sleeve 200 may traverse the central portion 106 of the connector pin 100 until the

protrusion 218 reaches the lock groove 122, whereby the protrusion engages the lock groove as shown in Figure 7.

The outer diameters of the catheters 60 and 70 may be slightly larger than the undeflected diameters 210 and 214 of the connector sleeve 200 (see Figure 5). Similarly, the diameter 210 may be sized to receive the central portion 106 of the pin connector 100 therein as shown in the figures. In other embodiments, the diameters 210 and 214 may be the same as, or slightly larger than, the corresponding catheters 60 and 70 and the central portions 106. The resulting fit between the sleeve and the catheters 60 and 70 and pin connector 100 assists in securing the sleeve in place. Moreover, the abutting relationship of the stop surface 120 (of the connector pin 100) with the stop surface 212 (of the connector sleeve 200) provides means to ensure proper longitudinal positioning, e.g., self-location, of the sleeve relative to the pin. Still further, the engagement of the protrusion 218 of the sleeve 200 with the groove 122 of the connector pin 100 provides positive feedback to the physician during connection and further prevents longitudinal separation, e.g., pulling apart, of the catheters 60 and 70.

While the stop surface 212 is shown herein as being generally perpendicular to the axis of the sleeve 200, other embodiments may provide other surface configurations. For example, a tapered surface may be used to form the stop surface.

Once the connector assembly 50 has been assembled as shown in Figure 7, it may be secured to surrounding tissue, e.g., sutured or ligated to scalp tissue, using the suture grooves 202. Preferably, a suture groove 202 is located over each side of the central portion 106, such that each catheter is effectively ligated by a suture.

The size of medical tubing connector assembly 50 may vary depending upon the size of the particular tubing to be connected. In one exemplary embodiment, the catheters 60 and 70 may have an undeflected lumen diameter of about 0.02 to about 0.03 inches (in), e.g., about 0.024 in (0.61 millimeters (mm)). The connector pin 100 may have a length of about 0.5 in (13 mm), while the outer diameter of each end portion 102 and 104 may be about 0.024 in (0.61 mm). The outer diameter of the enlarged central portion 106 may be about 0.085 in (2.16 mm), while the outer diameter of the first catheter 60 and the second catheter 70 may be about 0.089 in (2.26 mm) and 0.041 in (1.04 mm), respectively. The sleeve 200 may have length of about 0.6 to about 1 in, e.g., about 0.8 in (20 mm), a first outer diameter (proximate the first end 204) of about 0.125 in (3.17 mm), a first inner diameter 210 of about 0.080 to about 0.10 in, e.g., about 0.094 in (2.4 mm), a second outer

diameter (proximate the second end 206) of about 0.088 in (2.23 mm), and a second inner diameter 214 of about 0.035 to about 0.050 in, e.g., about 0.046 in (1.17 mm).

Connector assemblies in accordance with embodiments of the present invention may provide a secure method and apparatus for connecting separate sections of medical tubing by using a two-piece connector assembly (connector pin and connector sleeve). Moreover, connector sleeves in accordance with embodiments of the present invention provide not only secure coupling, but also strain relief to the catheter connection. For instance, when assembled, the sleeve 200 preferably extends a first distance 222 beyond the end of the first end portion 102 of the pin connector 100 (see Figure 7) and a second distance 224 beyond the second end portion 104. That is, a longitudinal length of the connector sleeve 200 is preferably greater than a longitudinal length of the connector pin 100. This construction may reduce the chance of the pin connector 100 puncturing the catheters.

The complete disclosure of the patents, patent documents, and publications cited in the Background, the Detailed Description of Exemplary Embodiments, and elsewhere herein are incorporated by reference in their entirety as if each were individually incorporated.

Exemplary embodiments of the present invention are described above. Those skilled in the art will recognize that many embodiments are possible within the scope of the invention. Other variations, modifications, and combinations of the various components and methods described herein can certainly be made and still fall within the scope of the invention. Thus, the invention is limited only by the following claims and equivalents thereto.

CLAIMS

What is claimed is:

1. A connector assembly for connecting sections of medical tubing, the assembly comprising:

a connector pin comprising:

a first end portion, a second end portion, and a lumen extending between the first end portion and the second end portion; and

a central portion located between the first end portion and the second end portion, wherein the central portion has an outer dimension that is larger than an outer dimension of both the first and second end portions; and

a tubular connector sleeve comprising a first end, a second end, and a passageway extending between the first end and the second end, the passageway being stepped such that it comprises: a first diameter between the first end of the sleeve and a stop surface located in the passageway; and a second diameter between the stop surface and the second end of the sleeve, wherein the first diameter is greater than the second diameter.

2. The connector assembly of claim 1, wherein the first diameter is sized to receive the central portion of the connector pin.

3. The connector assembly of any of claims 1-2, wherein the first diameter of the passageway comprises a first lock portion operable to engage a second lock portion formed on the central portion.

4. The connector assembly of claim 3, wherein the first lock portion comprises a protrusion extending inwardly from a wall of the passageway of the connector sleeve, and the second lock portion comprises a groove formed on an outer surface of the central portion of the connector pin.

5. The connector assembly of any of claims 1-4, wherein the sleeve comprises a polymer.

6. The connector assembly of any of claims 1-5, wherein the sleeve comprises one or more suture grooves on an exterior surface.

7. The connector assembly of any of claims 1-5, wherein the sleeve comprises two suture grooves on an exterior surface.

8. The connector assembly of any of claims 1-7, wherein each of the first end portion, the second end portion, and the central portion are substantially cylindrical in shape.

9. The connector assembly of any of claims 1-8, wherein a longitudinal length of the sleeve is greater than a longitudinal length of the connector pin.

10. The connector assembly of any of claims 1-9, wherein the stop surface is operable to abut the central portion of the connector pin when the connector assembly is assembled.

11. The connector assembly of any of claims 1-10, wherein the connector pin comprises a noble metal.

12. The connector assembly of any of claims 1-10, wherein the connector pin comprises titanium.

13. A method of interconnecting sections of medical tubing, the method comprising:
inserting a first end portion of a connector pin into a first medical tube, the connector pin comprising:
a second end portion, wherein a lumen extends between the first end portion and the second end portion; and
a central portion located between the first and second end portions, the central portion comprising an outer dimension that is greater than an outer dimension of either of the first and second end portions;
inserting the second end portion into a second medical tube;
sliding a tubular sleeve over the first and second medical tubes and the connector pin; and
engaging a first lock portion located within a passageway of the sleeve with a second lock portion of the connector pin.

14. The method of claim 13, further comprising sliding the sleeve over the first medical tube prior to inserting the first end portion of the connector pin therein.

15. The method of any of claims 13-14, wherein the first and second medical tubes are catheters.

16. The method of any of claims 13-15, further comprising securing the sleeve to tissue.

17. The method of any of claims 13-16, wherein securing the sleeve to tissue comprises suturing the sleeve to the tissue.

18. The method of any of claims 13-17, further comprising delivering a substance from the first medical tube to the second medical tube through the connector pin.

19. The method of any of claims 13-18, wherein sliding the sleeve over the first and second medical tubes and the connector pin comprises sliding the sleeve over the first and second medical tubes and the connector pin until a first stop surface within the passageway of the sleeve contacts a second stop surface associated with the central portion of the connector pin.

20. The method of any of claims 13-19, wherein engaging the first lock portion located within the passageway of the sleeve with the second lock portion of the connector pin comprises deforming the sleeve sufficiently for an inwardly extending protrusion located within the passageway of the sleeve to engage a groove formed in the central portion of the connector pin.

21. The method of any of claims 13-20, wherein sliding the sleeve over the first and second medical tubes and the connector pin comprises sliding the sleeve until it extends longitudinally beyond first and second ends of the connector pin.

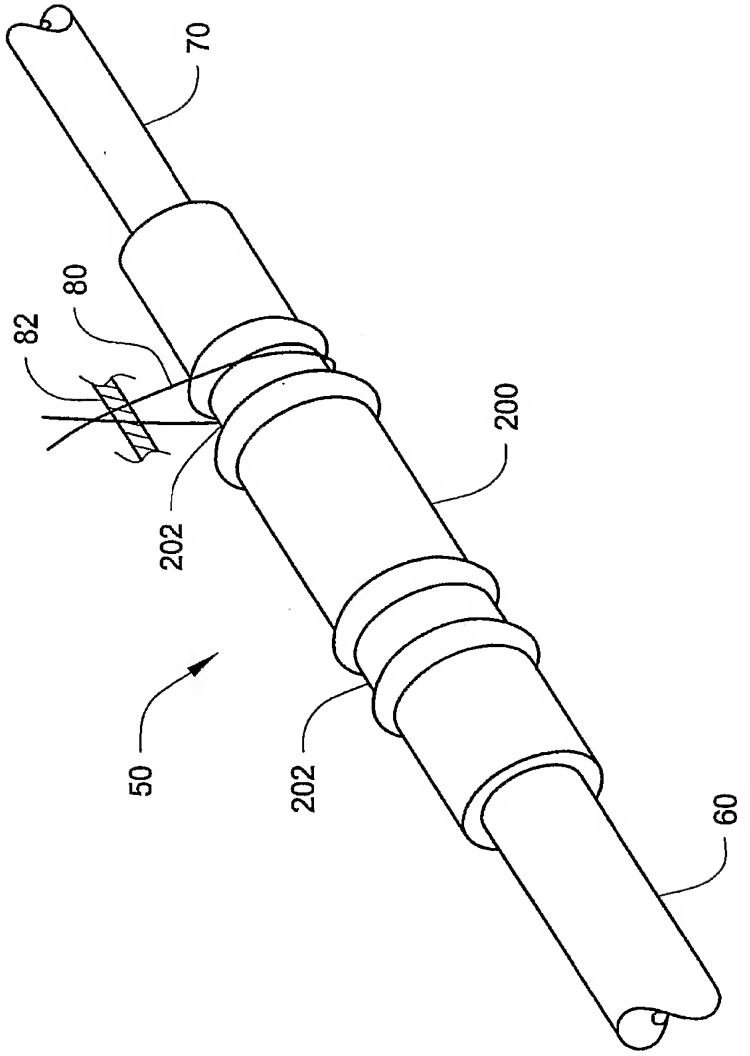


Fig. 1

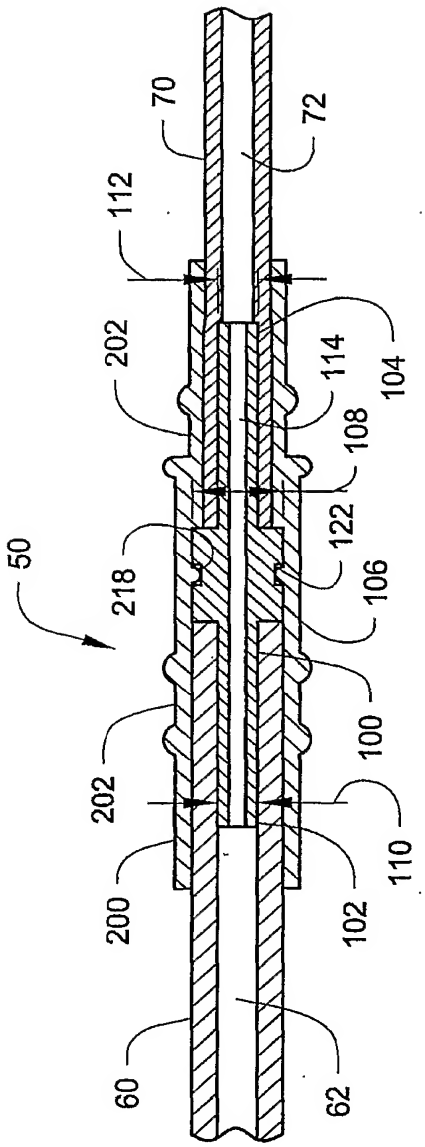


Fig. 2

Fig. 3

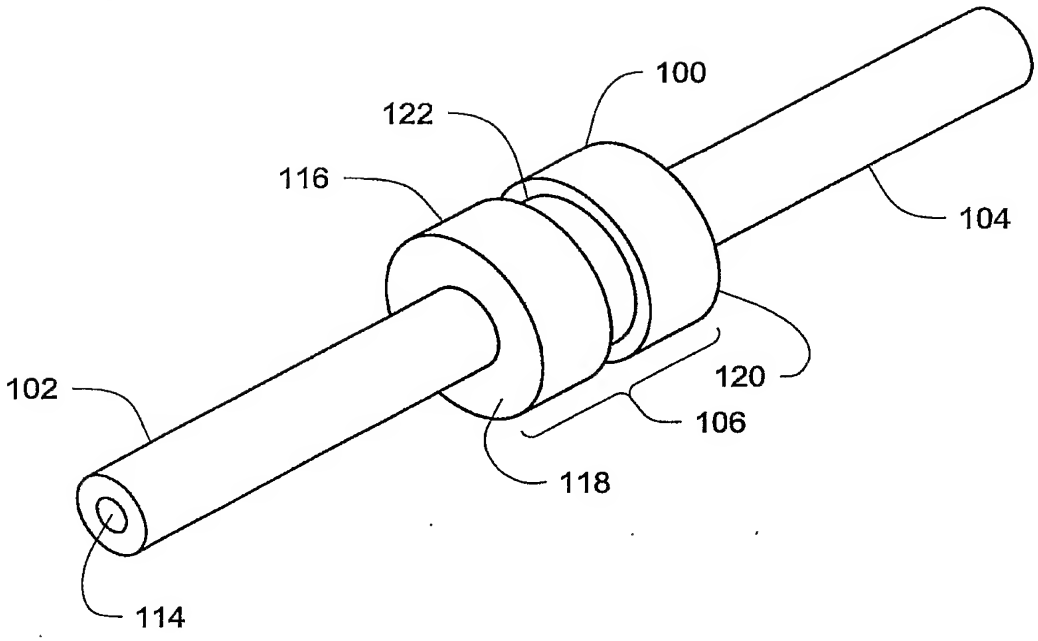


Fig. 4

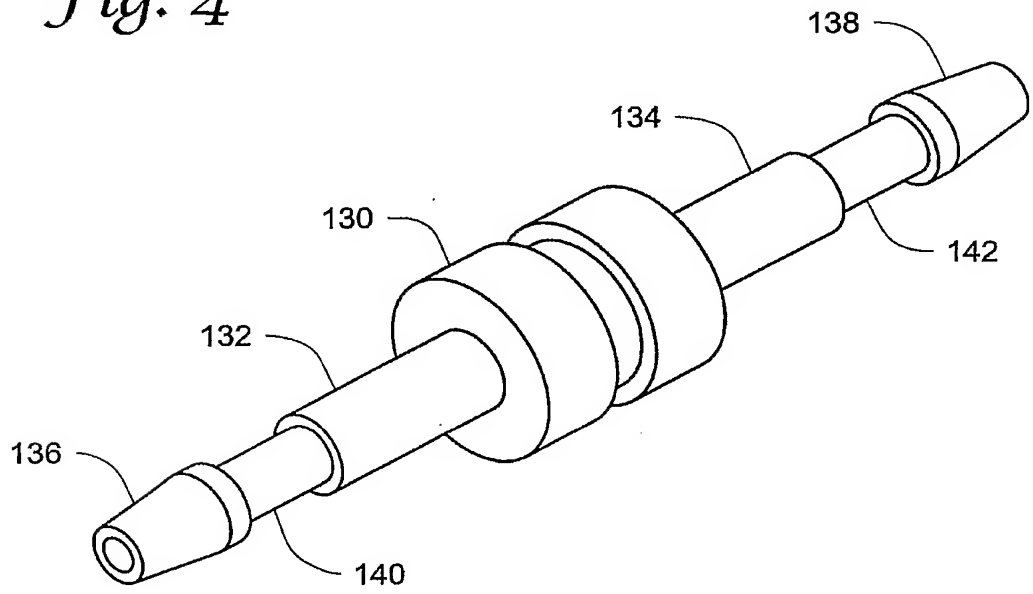


Fig. 5

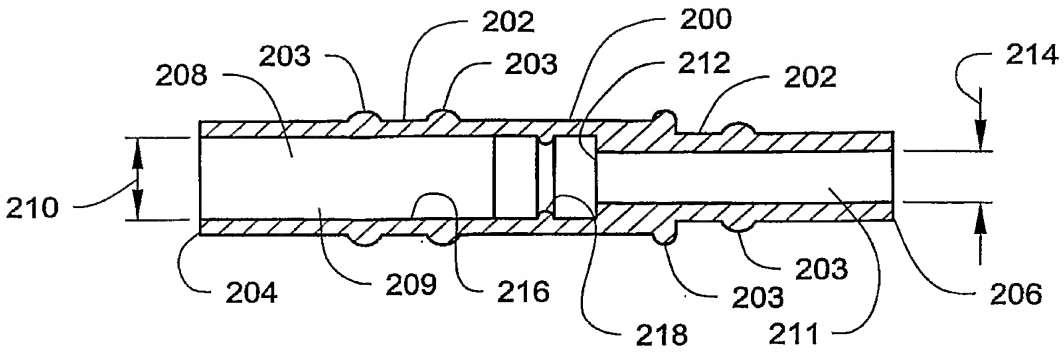


Fig. 6

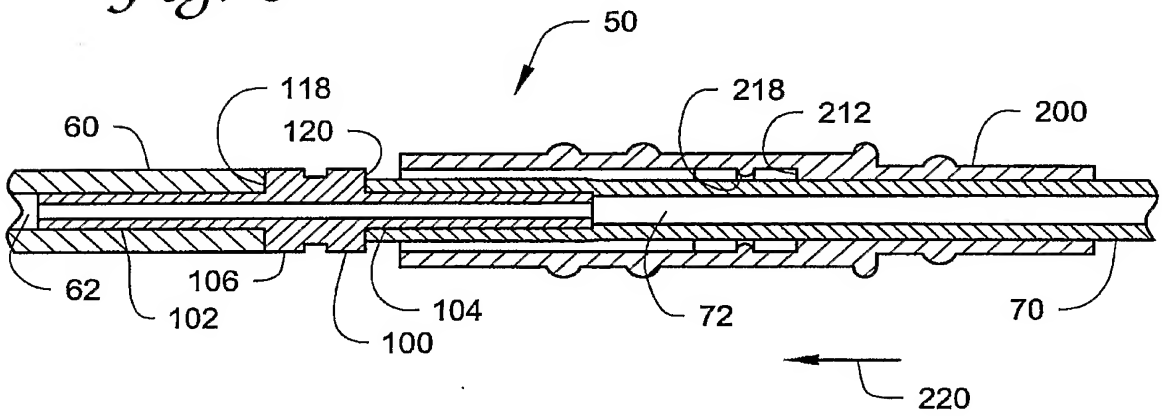
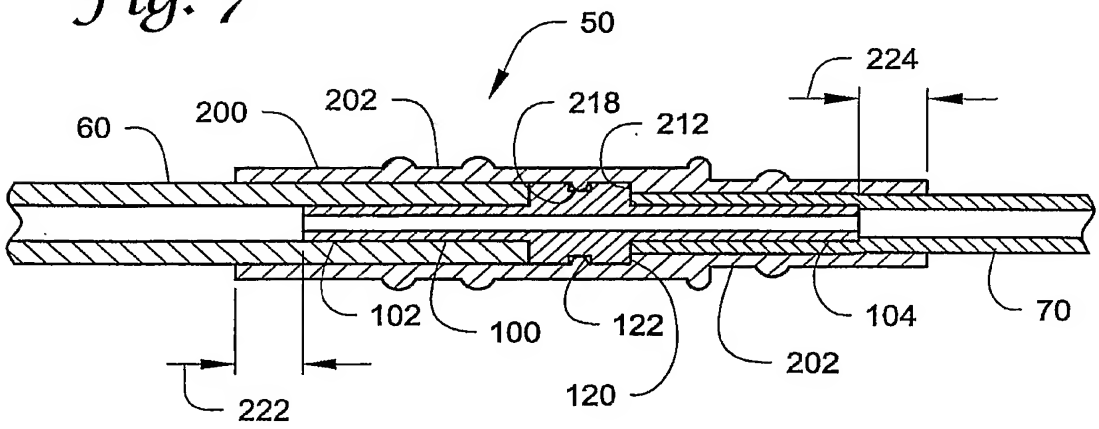


Fig. 7



INTERNATIONAL SEARCH REPORT

PCT/US2004/015464

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/00 A61M39/10 F16L31/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M F16L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 2 815 227 A (CULLEN ROY H ET AL) 3 December 1957 (1957-12-03) column 1, line 62 - column 4, line 27; figures 1-3	1-12 1-12
Y	AU 21021 83 A (ABBOTT LABORATORIES) 16 May 1985 (1985-05-16) page 5, line 5 - page 8, line 32; figure 2	1-12
A	DE 24 56 166 A1 (PERROT-REGNERBAU GMBH & CO) 12 August 1976 (1976-08-12) figure 1	1-12
A	WO 97/25562 A (MEFI MANAGEMENT AG; HAENER, GOTTFRIED) 17 July 1997 (1997-07-17) figure 2a	1-12

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
7 February 2005	17/02/2005

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Cuiper, R

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INTERNATIONAL SEARCH REPORT

PCT/US2004/015464

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 913 852 A (MAGRAM ET AL) 22 June 1999 (1999-06-22) figure 11	1-12

3

INTERNATIONAL SEARCH REPORT

application No.
PCT/US2004/015464

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 13-21
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

on patent family members

PCT/US2004/015464

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2815227 A	03-12-1957	NONE	
AU 2102183 A	16-05-1985	NONE	
DE 2456166 A1	12-08-1976	NONE	
WO 9725562 A	17-07-1997	AU 1188097 A WO 9725562 A1	01-08-1997 17-07-1997
US 5913852 A	22-06-1999	US 5772261 A	30-06-1998